DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/7/2011 has been entered. No new claims have been added. Claims 20, 22, 30 and 41-43 has been canceled.

Applicant's arguments filed 10/07/2011 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

(1) Claims 19, 21, 24-27, 29, 32-36 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lydzinski et al. (US 2003/00999692) in view of McCready et al. (Anal. Chem., 1950).

Lydzinski et al. is discussed previously as it discloses oral films comprised of starches including natural starches derived from legumes such as peas present in amounts ranging from about 50 to about 100%, the claimed secondary film forming components in amounts of less than 15%, and the claimed plasticizers in amounts from 0 to about 15%, which may be directly coated or sprayed onto another product such as a tablet. The starches may be modified, i.e hydroxypropylated.

Lydzinski et al. do not teach the amylose content of the instant claims.

McCready et al. is discussed previously as it discloses pea starch varieties including smooth peas which have an amylose content of 35% and 37%.

McCready et al. do not teach a film forming composition.

At the time of the invention, it would have been obvious to modify the composition of Lydzinski et al. to include the smooth pea starch of McCready et al. since Lydzinski et al. teaches the use of legumes such as peas. It would have been within the purview of the skilled artisan to use any source of peas and to evaluate its usefulness in the invention based on the broad disclosure of "sources of starches are legumes such as peas" of Lydzinski et al. It would have also been obvious to use a hydroxypropylated smooth pea starch since Lydzinski et al. teaches hydroxypropylated legume starches.

In regards to claims 29 and 32-34, the prior art does not specifically teach a pulverulent composition. However, the starch and the secondary film forming agent are in a dry form, i.e. powders or granules. It would be well within the purview of the skilled artisan to combine the two components to form a pulverulent composition to which the other components are added.

In regards to claims 29 and 33, the prior art does not teach the specific weight percentages of the hydroxypropylated starch or of the secondary film-forming agent; or the weight percentage of the plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15 to 75% of instant claims 29; that the starch component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claims 29; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claims 33.

In regards to claim 32, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the

starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claims 32.

In regards to claim 35, since the composition of the prior art are comprised of substantially the same components as those of the instant claim, it would reasonably be expected to exhibit substantially the same viscosity as the instant invention.

Applicant argues that McCready et al. fails to indicate any preference for smooth pea starch. Of the eight peas and pea starch varieties disclosed by McCready in Table III, only three are smooth, i.e. the majority of the pea starches listed by McCready have an amylose content greater than the claimed between 30 and 40% amylose. Lydzinski solely illustrates the use of modified high amylose or waxy corn starches with more than 5% amylose, and native tapioca starch. The only mention of pea starch by Lydzinski is relative to the native starch source. There is no suggestion that a starch having a 30-40% amylose content, such as pea starch, is preferred.

The Examiner disagrees.

A prior art reference is evaluated for all that it reasonably suggests and is not limited to working examples or preferred embodiments. Further, since this is a 103 obviousness rejection, no one piece of prior art is required to teach each and every limitation of the claims. As discussed by Applicant, Lydzinski et al. disclose the use of native starch sources such as pea starch. This provides the motivation for using the pea starches of McCready as the native starch source or at least to try with a reasonable expectation of success. As discussed by Applicant, McCready et al.

disclose eight varieties of pea starch, i.e. a finite number of options. It would be obvious to try each starch to determine which would provide the best results as it would have been obvious that some variation would be expected from different varieties of pea starches.

Applicant argues that even if one would have randomly selected smooth pea starch from McCready, there would have been no expectation of superior results of the claimed "film-forming starchy composition as demonstrated in Table 3. Table 3, rates the film/coating properties for various prepared starch compositions on a scale of "+++" (best) to "0" (worst), which is further explained in the newly executed Declaration. The compositions include those disclosed in Lydzinski, such as waxy starch, high amylose starch and modifications that include hydroxypropylation. The amylose contents greater than the claimed range and different types of modification are all disclosed in Lydzinski. The Declaration of Phileppe Lefevre is presented to provide support for the allegation of unexpected and surprising results. Lefevre declares that the Figures 1 and 2 of Annex 2 show tablets having a quotation of "+++" for all of the evaluated criteria; Figures 3 and 4 show tablets having a quotation "0" of all of the evaluated criteria; and that essentially the same results as those obtained in Example 1 of the present application when using pea starch (35/39% amylose) were obtained when using pea starch having an amylose content of 30% to 40%. Lefevre also provides a definition for the rankings in Table 3, i.e. "+++", "++", "+" and "0".

The Examiner disagrees.

The photos provide in the Annexes in the declaration do not support the allegation of unexpected results as they only depict the best case scenario, i.e. when all evaluated criteria are "+++" and the worst case scenario, i.e. when all evaluated criteria are "0". However the data for the starches of Example 1, Table 3, reveal that one of the tested starches provide the best case scenario and that all other starches produce results that fall somewhere in between. Accordingly, the photos are not representative of the other tested compositions, and therefore no determination of unexpected results can be made based on the pictures. Further, as disclosed in the declaration, the difference between "+++" and "++" has not been established to be of statistical significance as to be deemed unexpected or surprising. For example, for the criteria of absence of agglomeration during coating, "++" signifies no tablets stuck together and less than 1% of tablets having traces of sticking, whereas that for "+++" is no tablets stuck together, no traces of sticking, i.e. no statistically significant difference has been established between the two definitions; and for the criteria of smooth appearance "++" includes non-homogeneous color only at the beginning and a low orange skin aspect, whereas "+++" includes homogenous color from beginning to end and no orange skin aspect without a magnifying glass, i.e. no statistically significant difference has been established between low orange skin aspect and orange skin aspect visible with a magnifying glass. Applicant has not provided any support that the differences provided by the combination of criteria for the claimed starches is statistically significant from the combination of criteria for the other starches, i.e. amylose rich corn starch or a mixture

of starches comprising 42% amylose, tested in Example 1 as to represent a surprising or unexpected result.

(2) Claims 31 and 44-46 stand rejected under Lydzinski et al. and McCready et al. as applied to claims 19, 21, 24-27, 29, 32-36 and 40, and further in view of Fuentes et al. (US 6,469,161).

Lydzinski et al. and McCready et al. are discussed *supra*.

Lydzinski et al. and McCready et al. do not teach a hydroxypropylated and fluidification-treated pea starch.

Fuentes et al. is discussed previously as it discloses an inexpensive fluidification process for chemically modified pea starch. Modifications include hydroxypropylation reactions. The starches are used in the food and pharmaceutical industries.

Fuentes et al. does not teach a composition specifically comprised of pea starch with an amylose content of 30% to 40%.

At the time of the invention, it would have been obvious to modify the hydroxypropylated pea starch suggested by combining Lydzinski et al. and McCready et al. with the methods of Fuertes et al. to inexpensively produce a hydroxypropylated and fluidification-treated starchy material with increased film strength for use in the pharmaceutical industry, i.e., in preparing pharmaceutical compositions, as taught by Fuertes et al.

The prior art does not teach the specific weight percentages of the hydroxypropylated starch or of the secondary film-forming agent; or the amount of

plasticizer. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach the starch is present in amounts ranging from about 50 to about 100% versus 15 to 75% of instant claim 31; that the starch component also comprises a cellulosic material or a gum in amounts of less than 15% versus the 1 to 20% of instant claim 31; and that the plasticizer in amounts from 0 to about 15% versus the 5 to 15% of instant claim 45.

In regards to claim 44, the prior art does not teach a combination of a film-forming agent and microcrystalline cellulose. However, generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly it would have been obvious to combine a cellulosic material, such as a hydroxyalkylcellulose and microcrystalline cellulose since both are taught to be film-forming agents individually. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Lydzinski et al. teach that the starch component also comprises a cellulosic material, such as microcrystalline cellulose in amounts of less than 15% versus the 1 to 20% of instant claim 44.

Applicant argues that for the reasons above, Lydzinski and McCready fail to render obvious a composition having an amylose content of between 30 and 40%' and Fuentes fails to remedy the shortcomings of Lydzinski and McCready.

The Examiner disagrees.

The Examiner's response to Applicant's arguments concerning Lydzinski et al. and McCready et al. are provided *supra*. Accordingly, Fuentes et al. is only required to provide motivation for combining. Since Fuentes et al. disclose inexpensive fluidification processes for starchy materials , it provides adequate motivation for combining with Lydzinski et al. and McCready et al.

(3) Claims 19, 28, 37-39 and 47 stand Haasmaa (US 2002/0032254) in view of McCready et al. (Anal. Chem., 1950), Leusner (US 4,431,800) and Kim et al. (US 6,123,963).

Haasma et al. is discussed previously as it discloses hydrophobic starch dispersions used for the production of films as well as coating medical preparations. The starch is pea starch, and is mixed with a plasticizer in an amount of 0.001-95%. The plasticizer is present in an amount of 0.1 to 2 times the starch.

Haasmaa et al. do not teach a stabilized starch which has an amylose content between 30% and 40%; or the amounts of stabilized peas starch and plasticizer; nor the coating process of claims 38 and 39.

McCready et al. is discussed *supra*.

McCready et al. does not teach a film forming composition.

Leusner et al. is discussed previously as it discloses hydroxypropylated starches have reduced or decreased tendency toward retrodegradation, i.e. improved stability.

Leusner does not teach a composition comprised of a stabilized pea starch.

Kim et al. is discussed previously as it discloses conventional processes for coating tablets, granules, pellets, crystals and capsules include dip coating and fluidized bed coating.

Kim et al. does not teach the film-forming compositions of claim 19.

At the time of the invention, it would have been obvious to modify the composition of Haasmaa et al. to include the smooth pea starch of McCready et al. since Haasmaa et al. teaches the use of native starches such as pea starch. It would have been within the purview of the skilled artisan to use any source of peas and to evaluate its usefulness in the invention based on the broad disclosure of "native starches such as pea starch" of Haasmaa et al.

At the time of the invention, it would have been obvious to modify the smooth pea starch suggested by combining Haasmaa et al. and McCready et al. with the methods of Leusner et al. to produce a hydroxypropylated pea starch for use as the starch component since it is a stable starch ether. It would have been obvious to use the starch composition suggested by combining Haasmaa et al., McCready et al. and Leusner et al. in coating processes of Kim et al. since it teaches that conventional methods of coating capsules include fluidized bed and dip-coating.

In regard to claim 28, the prior art does not teach the specific amounts of stabilized pea starch and plasticizer. The prior art does not disclose the exact claimed

values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Haasmaa et al. teaches amounts of plasticizer of 0.01 to 95% versus plasticizer in amounts of 1-2%; and that the amount of plasticizer will be from 0.1 to 2 times the amount of the starch component, i.e. the starch component can be from 0.1 to 47.5%, versus stabilized pea starch in amounts of 10 to 15% of the instant claim.

Applicants argue that Haasmaa does not provide guidance for the selection of a starch having an amylose content between 30% and 40%. Haasmaa simply provides an exhaustive list of starch sources with amylose content between 0 and 100%. Barley or at least cereal starches appear to be preferred in the Examples. As noted above McCready fails to indicate any preference for smooth pea starch. Neither Leusner nor Kim provides any guidance for selecting a starch with an amylose content of between 30% and 40%. Applicant reiterates the arguments presented *supra* regarding the Declaration of Philippe Lefevre.

The Examiner disagrees.

Applicant's arguments are substantially the same as discussed *supra*. Accordingly, the Examiner's arguments provided *supra* are applicable, since Haasmaa et al. disclose pea starch as a native starch source in amounts of 0.1% to 47.5%.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612